

JAN 21 2005

Ophthalmic Technologies Inc.  
Special 510(k) Submission  
OCT- Ophthalmoscope

K042885

510(k) Summary  
September 30, 2004

(1) Submitter Information

Name: Ophthalmic Technologies Inc.

Address:

Ophthalmic Technologies Inc.  
37 Kodiak Crescent, Unit 16  
Downsview, Ontario, Canada M3J 3E5

Telephone number:

416-631-9123 • 1-800-517-4444

Contact Person:  
Dr. George Myers (Official Correspondent)  
Medsys Inc.  
377 Route 17 S  
Hasbrouck Heights, NJ 07604  
Telephone 201-727-1703  
Fax 201-727-1708

Date Prepared: December 10, 2002

(2) Name of Device

Trade Name: OCT- Ophthalmoscope  
Common Name: Ophthalmoscope using optical coherence tomography  
Classification name: Ophthalmoscope, a-c powered, 890111

(3) Equivalent legally-marketed devices.

K012727, Optical Coherence Tomography Model 3000, Zeiss Ophthalmic Systems  
K943956, Retina Tomograph and Flowmeter, Heidelberg Engineering

(4) Description

The OTI OCT Ophthalmoscope produces simultaneous acquisition of high-resolution transversal OCT (Optical Coherence Tomography) and confocal images of

the eye fundus. In addition conventional longitudinal OCT images may also be collected.

The system uses a high power superluminescent diode operating at 850nm. The software uses a tabbed interface: the user can select any of the primary functional modules at any time by clicking on the tab for that function at the top of the screen. When there are several major components in a function, these are presented as tabs below the principal tab bar.

#### (5) Intended Use

The OTI OCT Ophthalmoscope is intended to offer simultaneous acquisition of high-resolution transversal OCT (Optical Coherence Tomography) and confocal images of the eye fundus. In addition conventional longitudinal OCT images may also be collected.

#### (6) Performance Data

##### (a) Non-clinical tests

The OCT-Ophthalmoscope has had accuracy tests, optical emissions analyses, electrical safety tests, and software validation tests.

##### (b) Clinical tests

Not required.

##### (c) Conclusions

The OCT-Ophthalmoscope is equivalent in safety and efficacy to the legally-marketed predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 21 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ophthalmic Technologies, Inc.  
c/o Medsys Inc.  
George Myers, Sc.D.  
377 Rt. 17 South  
Hasbrouck Heights, N.J 07604

Re: K042885  
Trade/Device Name: OCT-Ophthalmoscope  
Regulation Number: 21 CFR 886.1570  
Regulatory Class: Class II  
Product Code: HLI  
Dated: October 17, 2004  
Received: November 18, 2003

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in cursive script that reads "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: OCT- Ophthalmoscope

## Indications for Use:

The OTI OCT Ophthalmoscope is intended to offer simultaneous acquisition of high-resolution transversal OCT (Optical Coherence Tomography) and confocal images of the eye fundus. It is indicated in situations where these images are required for diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
Use \_\_\_\_\_  
(Per 21 CFR 810.109)

OR

Over-the-Counter

(Optional Format 1-2-96)

Denis L. McCauley

(Division Sign-Off)

Division of Ophthalmic Ear,  
Nose and Throat Devices510(k) Number K042885